

MICHIGAN DEPARTMENT OF ~~PUBLIC COMMUNITY HEALTH~~
~~OFFICE OF HEALTH AND MEDICAL AFFAIRS~~

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR
COMPUTED TOMOGRAPHY (CT) SCANNER SERVICES

(By authority conferred on the ~~Certificate of Need~~CON Commission by Sections ~~22215 and 22217~~ of Act No. 368 of the Public Acts of 1978, as amended, and Sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being Sections 333.22215, ~~333.22217~~, 24.207 and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for the approval and delivery of services for all projects approved and certificates of need issued under Part 222 of the Code which involve CT scanners.

(2) ~~A~~CT scanner is ~~A~~covered ~~medical equipment~~CLINICAL SERVICE for purposes of Part 222 of the Code.

(3) The department shall use Sections 3, 4, 5, 6, ~~913~~, and ~~1014~~, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(4) The department shall use Sections ~~7-11~~ and ~~812~~, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

Sec. 2. (1) For purposes of these standards:

(a) ~~"Acquire~~ACQUISITION OF a CT scanner.SERVICE" means obtaining possession or control of a CT scanner.SERVICE AND ITS UNIT(S), whether fixed or mobile, by contract, ownership, or otherwise. For proposed projects involving mobile CT scanners this applies to the central service coordinator and/or host facility.

(b) "Billable procedure" means a CT procedure or set of procedures commonly billed as a single unit.

(c) "Body scans" include all spinal CT scans and any CT scan of an anatomical site below and including the neck.

(d) "Central service coordinator" means the organizational unit which has operational responsibility for a mobile CT scanner and which is a legal entity authorized to do business in the state of Michigan.

~~(E) "CERTIFICATE OF NEED COMMISSION" OR "COMMISSION" MEANS THE COMMISSION CREATED PURSUANT TO SECTION 22211 OF THE CODE, BEING SECTION 333.22211 OF THE MICHIGAN COMPILED LAWS.~~

~~(e)~~F) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 ~~et seq.~~ of the Michigan Compiled Laws.

~~(f)~~G) "Computed tomography" or "CT" means the use of radiographic and computer techniques to produce cross-sectional images of the head or body.

~~(g)~~H) "CT equivalents" means the resulting number of units produced when the number of billable procedures for each category is multiplied by its respective conversion factor tabled in Section 9.

~~(h)~~I) "CT scanner" means x-ray CT scanning systems capable of performing either head or full body patient procedures INCLUDING POSITRON EMISSION TOMOGRAPHY (PET)/CT SCANNER HYBRIDS IF USED FOR CT ONLY PROCEDURES. The term does not include emission-computed tomographic systems utilizing internally administered single-photon gamma ray emitters, positron annihilation CT systems, magnetic resonance, ultrasound computed tomographic systems, or similar technology.

~~(i)~~J) "CT scanner equipment," for purposes of sections 3 and 5 of these standards, means the equipment necessary to perform CT scans. It does not include any construction or renovations activities

associated with the installation of the CT scanner, or service or maintenance contracts which under generally accepted accounting principles are properly chargeable as an expense of operation.

(K) "DEPARTMENT" MEANS THE MICHIGAN DEPARTMENT OF COMMUNITY HEALTH (MDCH).

(L) "Driving time," for purposes of these standards, means the driving time in minutes as identified in the Michigan Department of Transportation Statewide Proximity Analysis BY USE OF MAPPING SOFTWARE THAT IS VERIFIABLE BY THE DEPARTMENT.

(M) "Emergency room" means a designated area physically part of a licensed hospital and recognized by the department as having met the staffing and equipment requirements for the treatment of emergency patients.

(N) "EXPAND A CT SCANNER SERVICE" MEANS THE ADDITION OF ONE OR MORE CT SCANNERS AT AN EXISTING CT SCANNER SERVICE.

(O) "Head scans" include head or brain CT scans; including the maxillofacial area; the orbit, sella, or posterior fossa; or the outer, middle, or inner ear; or any other CT scan occurring above the neck.

(P) "Host facility" means the site at which a mobile CT scanner is located in order to provide CT scanner services.

(Q) "INITIATE A CT SCANNER SERVICE" MEANS TO BEGIN OPERATION OF A CT SCANNER, WHETHER FIXED OR MOBILE, AT A SITE THAT DOES NOT PERFORM CT SCANS AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT. THE TERM DOES NOT INCLUDE THE ACQUISITION OR RELOCATION OF AN EXISTING CT SCANNER SERVICE OR THE RENEWAL OF A LEASE.

(R) "MEDICAID" MEANS TITLE XIX OF THE SOCIAL SECURITY ACT, CHAPTER 531, 49 STAT. 620, 1396R-6 AND 1396R-8 TO 1396V.

(S) "Mobile CT scanner SERVICE" means a CT scanner and transporting equipment operated by a central service coordinator and which must serve two or more host facilities.

(T) "Mobile CT scanner network" means the route (all host facilities) the mobile CT scanner is authorized to serve.

(U) "RELOCATE AN EXISTING CT SCANNER SERVICE" MEANS A CHANGE IN THE GEOGRAPHIC LOCATION OF AN EXISTING FIXED CT SCANNER SERVICE AND ITS UNIT(S) FROM AN EXISTING SITE TO A DIFFERENT SITE.

(V) "RELOCATION ZONE," FOR PURPOSES OF THESE STANDARDS, MEANS A SITE THAT IS WITHIN A 10-MILE RADIUS OF A SITE AT WHICH AN EXISTING FIXED CT SCANNER SERVICE IS LOCATED IF AN EXISTING FIXED CT SCANNER SERVICE IS LOCATED IN A NON-RURAL COUNTY, OR A 20-MILE RADIUS IF AN EXISTING FIXED CT SCANNER SERVICE IS LOCATED IN A RURAL COUNTY.

(W) "Replace/upgrade a CT scanner" means an equipment change proposed by an applicant which results in that applicant operating the same number of CT scanners before and after project completion.

(X) "RURAL COUNTY" MEANS A COUNTY NOT LOCATED IN A METROPOLITAN STATISTICAL AREA OR MICROPOLITAN STATISTICAL AREAS AS THOSE TERMS ARE DEFINED UNDER THE 'STANDARDS FOR DEFINING METROPOLITAN AND MICROPOLITAN STATISTICAL AREAS' BY THE STATISTICAL POLICY OFFICE OF THE OFFICE OF INFORMATION AND REGULATORY AFFAIRS OF THE UNITED STATES OFFICE OF MANAGEMENT AND BUDGET, 65 F.R. P. 82238 (DECEMBER 27, 2000) AND AS SHOWN IN APPENDIX A.

(2) The definitions in Part 222 shall apply to these standards.

Section 3. Requirements for approval for applicants proposing to ~~acquire their first~~ INITIATE A CT scanner SERVICE

Sec. 3. In order to be approved, an applicant proposing to ~~acquire its first~~ INITIATE A CT scanner SERVICE shall demonstrate each of the following, as applicable:

(1) A hospital proposing to ~~acquire~~ INITIATE its first fixed CT scanner SERVICE, ~~with a capital expenditure associated with the CT scanner equipment of greater than \$750,000;~~ shall demonstrate each

of the following:

(a) ~~The hospital shall project an operating level of at least 3,500 CT equivalents for the second 12 month period after beginning operation of the CT scanner.~~

~~—(b)—~~ The proposed site is a hospital licensed under Part 215 of the Code.

(eB) The hospital operates an emergency room THAT PROVIDES 24-HOUR EMERGENCY CARE SERVICES AS AUTHORIZED BY THE LOCAL MEDICAL CONTROL AUTHORITY TO RECEIVE AMBULANCE RUNS.

~~—(d)—~~ The capital expenditure associated with the acquisition of the CT scanner equipment is greater than \$750,000.

~~—(2)—~~ A hospital proposing to acquire its first fixed CT scanner, with a capital expenditure associated with the CT scanner equipment of \$750,000 or less, shall demonstrate each of the following:

~~—(a)—~~ The hospital shall project an operating level of at least 1,500 CT equivalents for the second 12 month period after beginning operation of the CT scanner. If the proposed hospital site is more than 60 minutes driving time from another fixed CT scanner that is available on a 24 hour basis (either through on-site or on-call staffing arrangements), subsection (a) shall not apply.

~~—(b)—~~ The proposed site is a hospital licensed under Part 215 of the Code.

~~—(c)—~~ The hospital operates an emergency room.

~~—(d)—~~ The capital expenditure associated with the acquisition of the CT scanner equipment is \$750,000 or less.

(32) An applicant, other than an applicant meeting all of the applicable requirements of subsection (1) ~~or (2)~~, proposing to ~~acquire its first~~ INITIATE A fixed CT scanner SERVICE shall project an operating level of at least 7,500 CT equivalents per year for the second 12 month period after beginning operation of the CT scanner.

(43) An applicant proposing to ~~acquire its first~~ INITIATE A mobile CT scanner SERVICE shall project an operating level of at least 3,500 CT equivalents per year for the second 12 month period after beginning operation of the CT scanner.

Section 4. Requirements ~~for additional~~ TO EXPAND A CT scanners SERVICE - all applicants

Sec. 4. (1) If an application ~~I~~ proposes ~~an additional~~ TO EXPAND A fixed CT scanner ~~(second, third, etc.), in addition to a fixed CT scanner previously approved for that same person at the same site, in order to be approved~~ SERVICE, the applicant shall demonstrate each of the following:

(a) The applicant shall project an average operating level of at least 7,500 CT equivalents for each fixed CT scanner, existing and proposed, operated by the applicant for the second 12 month period after initiation of operation of each additional CT scanner.

(b) All of the applicant' s fixed CT scanners have performed an average of at least 10,000 CT equivalents per fixed CT scanner for the most recent continuous 12 month period preceding the applicant' s request. In computing this average the department will divide the total number of CT equivalents performed by the applicant' s total number of fixed CT scanners, including both operational and approved but not operational fixed CT scanners.

(2) If an application ~~I~~ proposes ~~an additional~~ TO EXPAND A mobile CT scanner ~~(second, third, etc.); in addition to a mobile CT scanner previously approved for that same person, in order to be approved~~ SERVICE, ~~that person~~ THE APPLICANT shall demonstrate each of the following:

(a) The applicant shall project an operating level of at least 4,000 CT equivalents for each existing and proposed mobile CT scanner for the second 12 month period after beginning operation of each additional CT scanner.

(b) All of the applicant' s mobile CT scanners have performed an average of at least 5,500 CT equivalents per mobile CT scanner for the most recent continuous 12 month period preceding the applicant' s request. In computing this average the department will divide the total number of CT

equivalents performed by the applicant' s total number of mobile CT scanners, including both operational and approved but not operational mobile CT scanners.

Section 5. Requirements for applications proposing to replace/upgrade a CT scanner

Sec. 5. In order to be approved, an applicant proposing to replace/upgrade an existing CT scanner shall demonstrate each of the following, as applicable:

(1) A hospital proposing to replace/upgrade an existing CT scanner which is the only fixed CT scanner operated at that site by the hospital, ~~with a capital expenditure associated with the replacement CT scanner equipment of greater than \$750,000~~, shall demonstrate each of the following:

~~(a) The existing CT scanner to be replaced/upgraded performed at least 3,500 CT equivalents during the 12 month period immediately preceding the date of the application.~~

~~—(b)—~~ The proposed site is a hospital licensed under Part 215 of the Code.

~~(eB)~~ The hospital operates an emergency room THAT PROVIDES 24-HOUR EMERGENCY CARE SERVICES AS AUTHORIZED BY THE LOCAL MEDICAL CONTROL AUTHORITY TO RECEIVE AMBULANCE RUNS.

~~—(d)—~~ The capital expenditure associated with the acquisition of the CT scanner equipment is greater than \$750,000.

~~(eC)~~ The replacement CT scanner will be located at the same site as the CT scanner to be replaced.

~~—(2)—~~ A hospital proposing to replace/upgrade an existing CT scanner which is the only fixed CT scanner operated at that site by the hospital, with a capital expenditure associated with the replacement CT scanner equipment of \$750,000 or less, shall demonstrate each of the following:

~~—(a)—~~ The existing CT scanner to be replaced/upgraded performed at least 1,500 CT equivalents during the 12 month period immediately preceding the date of the application. If the existing hospital site is more than 60 minutes driving time from another fixed CT scanner that is available on a 24 hour basis (either through on-site or on-call staffing arrangements), subsection (a) shall not apply.

~~—(b)—~~ The proposed site is a hospital licensed under Part 215 of the Code.

~~—(c)—~~ The hospital operates an emergency room.

~~—(d)—~~ The capital expenditure associated with the acquisition of the replacement CT scanner equipment is \$750,000 or less.

~~—(e)—~~ The replacement CT scanner will be located at the same site as the CT scanner being replaced.

~~(32)~~ An applicant, other than an applicant meeting all of the applicable requirements of subsection (1) ~~or (2)~~, proposing to replace/upgrade an existing fixed CT scanner shall demonstrate that the volume of CT equivalents, during the 12 month period immediately preceding the date of the application, performed by the CT scanner to be replaced/upgraded was at least 7,500 CT equivalents if the applicant operates only one fixed CT scanner, or an average of 7,500 CT equivalents for each fixed CT scanner if the applicant operates more than one fixed CT scanner at the same site.

~~(43)~~ An applicant proposing to replace/upgrade an existing mobile CT scanner(s) shall demonstrate that the volume of CT equivalents, during the 12 month period immediately preceding the date of the application, performed by the CT scanner to be replaced/upgraded was at least 3,500 CT equivalents if the applicant operates only one mobile CT scanner or an average of 5,500 CT equivalents for each CT scanner if the applicant operates more than one mobile CT scanner for the same mobile CT scanner network.

~~(54)~~ An applicant under this section shall demonstrate that the CT scanner(s) proposed to be replaced/upgraded is fully depreciated according to generally accepted accounting principles, or, that the existing equipment clearly poses a threat to the safety of the public, or, that the proposed replacement/upgraded CT scanner offers technological improvements which enhance quality of care, increase efficiency, and/or reduce operating costs and patient charges.

SECTION 6. REQUIREMENTS FOR APPROVAL FOR APPLICANTS PROPOSING TO RELOCATE AN EXISTING CT SCANNER SERVICE

SEC. 6. AN APPLICANT PROPOSING TO RELOCATE ITS EXISTING CT SCANNER SERVICE AND ITS UNIT(S) SHALL DEMONSTRATE THAT THE PROPOSED PROJECT MEETS ALL OF THE FOLLOWING:

(1) THE CT SCANNER SERVICE AND ITS UNIT(S) TO BE RELOCATED IS A FIXED CT SCANNER UNIT(S).

(2) THE CT SCANNER SERVICE TO BE RELOCATED HAS BEEN IN OPERATION FOR AT LEAST 36 MONTHS AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(3) THE PROPOSED PROJECT WILL NOT RESULT IN THE REPLACEMENT OF THE CT SCANNER UNIT(S) OF THE SERVICE TO BE RELOCATED UNLESS THE APPLICANT DEMONSTRATES THAT THE REQUIREMENTS OF SECTION 5, AS APPLICABLE, ALSO HAVE BEEN MET.

(4) THE PROPOSED PROJECT WILL NOT RESULT IN AN INCREASE IN THE NUMBER OF FIXED UNIT(S) BEING OPERATED BY THE CT SCANNER SERVICE THAT IS PROPOSED TO BE RELOCATED.

(5) THE PROPOSED SITE TO WHICH THE CT SCANNER SERVICE IS PROPOSED TO BE RELOCATED IS IN THE RELOCATION ZONE.

(6) THE CT SCANNER SERVICE AND ITS UNIT(S) TO BE RELOCATED PERFORMED AT LEAST AN AVERAGE OF 7,500 CT EQUIVALENTS PER FIXED UNIT IN THE MOST RECENT 12-MONTH PERIOD, OR MOST RECENT ANNUALIZED 6-MONTH PERIOD, FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

(7) THE APPLICANT AGREES TO OPERATE THE CT SCANNER SERVICE AND ITS UNIT(S) IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN SECTION 11 OF THESE STANDARDS.

SECTION 7. REQUIREMENTS FOR APPROVAL FOR APPLICANTS PROPOSING TO ACQUIRE AN EXISTING CT SCANNER SERVICE AND ITS UNIT(S)

SEC. 7. AN APPLICANT PROPOSING TO ACQUIRE AN EXISTING FIXED OR MOBILE CT SCANNER SERVICE AND ITS UNIT(S) SHALL DEMONSTRATE THAT A PROPOSED PROJECT MEETS ALL OF THE FOLLOWING:

(1) THE PROJECT WILL NOT RESULT IN THE REPLACEMENT OF THE CT SCANNER UNIT AT THE CT SCANNER SERVICE TO BE ACQUIRED UNLESS THE APPLICANT DEMONSTRATES THAT THE REQUIREMENTS OF SECTION 5, AS APPLICABLE, ALSO HAVE BEEN MET.

(2) THE PROJECT WILL NOT RESULT IN A CHANGE IN THE SITE AT WHICH THE EXISTING CT SCANNER SERVICE AND ITS UNIT(S) IS OPERATED UNLESS THE PROPOSED PROJECT MEETS THE REQUIREMENTS OF SECTION 6.

(3) THE PROJECT WILL NOT CHANGE THE NUMBER OF CT SCANNER UNIT(S) AT THE SITE OF THE CT SCANNER SERVICE BEING ACQUIRED UNLESS THE APPLICANT DEMONSTRATES THAT PROJECT IS IN COMPLIANCE WITH THE REQUIREMENTS OF SECTION 4 AS APPLICABLE.

____(4) FOR AN APPLICATION FOR THE PROPOSED FIRST ACQUISITION OF AN EXISTING FIXED OR MOBILE CT SCANNER SERVICE, FOR WHICH A FINAL DECISION HAS NOT BEEN ISSUED AFTER THE EFFECTIVE DATE OF THESE STANDARDS, AN EXISTING CT SCANNER SERVICE TO BE ACQUIRED SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE VOLUME REQUIREMENT APPLICABLE TO THE SELLER/LESSOR ON THE DATE THE ACQUISITION OCCURS. THE CT SCANNER SERVICE AND ITS UNIT(S) SHALL BE OPERATING AT THE APPLICABLE VOLUME REQUIREMENTS SET FORTH IN SECTION 11 OF THESE STANDARDS IN THE SECOND 12 MONTHS AFTER THE DATE THE SERVICE AND ITS UNIT(S) IS ACQUIRED, AND ANNUALLY THEREAFTER.

____ (5) FOR ANY APPLICATION FOR PROPOSED ACQUISITION OF AN EXISTING FIXED OR MOBILE CT SCANNER SERVICE, EXCEPT THE FIRST APPLICATION APPROVED PURSUANT TO SUBSECTION (3), FOR WHICH A FINAL DECISION HAS NOT BEEN ISSUED AFTER THE EFFECTIVE DATE OF THESE STANDARDS, AN APPLICANT SHALL BE REQUIRED TO DEMONSTRATE THAT THE CT SCANNER SERVICE AND ITS UNIT(S) TO BE ACQUIRED PERFORMED AT LEAST 7,500 CT EQUIVALENTS IN THE MOST RECENT 12-MONTH PERIOD, OR MOST RECENT ANNUALIZED 6-MONTH PERIOD, FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

SECTION 8. REQUIREMENTS FOR APPROVAL OF A PET/CT HYBRID FOR INITIATION, EXPANSION, REPLACEMENT, AND ACQUISITION

SEC. 8. AN APPLICANT PROPOSING TO INITIATE, EXPAND, REPLACE, OR ACQUIRE A PET/CT HYBRID SHALL DEMONSTRATE THAT IT MEETS ALL OF THE FOLLOWING:

(1) THERE IS AN APPROVED PET CON FOR THE PET/CT HYBRID, AND THE PET/CT HYBRID IS IN COMPLIANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS AS SET FORTH IN THE CON REVIEW STANDARDS FOR PET.

(2) THE APPLICANT AGREES TO OPERATE THE PET/CT HYBRID IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN SECTION 11 OF THESE STANDARDS.

(3) THE APPROVED PET/CT HYBRID WILL NOT BE SUBJECT TO CT VOLUME REQUIREMENTS.

(4) A PET/CT SCANNER HYBRID APPROVED UNDER THE CON REVIEW STANDARDS FOR PET SCANNER SERVICES AND THE REVIEW STANDARDS FOR CT SCANNER SERVICES MAY NOT UTILIZE CT PROCEDURES PERFORMED ON A HYBRID UNIT TO DEMONSTRATE NEED OR TO SATISFY CT CON REVIEW STANDARDS REQUIREMENTS.

Section 69. Additional requirements for approval of A mobile CT scanners~~s~~SERVICE

Sec. 69. (1) An applicant proposing to ~~begin operation of~~INITIATE a mobile CT scanner SERVICE in Michigan shall demonstrate that it meets all of the following:

(a) A separate ~~certificate of need~~ CON application shall be submitted by the central service coordinator and each Michigan host facility.

(b) The normal route schedule, the procedures for handling emergency situations, and copies of all potential contracts related to the mobile CT scanner SERVICE shall be included in the ~~certificate of need~~CON application submitted by the central service coordinator.

(c) The requirements of ~~Section~~ Section S 3, 4, or 5, as applicable, have been met.

(2) An applicant proposing to become a host facility on an existing mobile CT scanner network shall

demonstrate that it meets all of the following:

(a) Approval of the application will not result in an increase in the number of operating mobile CT scanners for the mobile CT scanner network unless the requirements of Section 4 have been met.

(b) A separate ~~certificate of need~~CON application has been filed for each host facility.

(3) An applicant proposing to replace a central service coordinator on an existing mobile CT scanner network shall demonstrate that approval of the application will not replace the CT scanner and transporting equipment unless the applicable requirements of Section 5 have been met.

Section 10. Requirements for approval -- all applicants

Sec. 10. AN APPLICANT SHALL PROVIDE VERIFICATION OF MEDICAID PARTICIPATION AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT. IF THE REQUIRED DOCUMENTATION IS NOT SUBMITTED WITH THE APPLICATION ON THE DESIGNATED APPLICATION DATE, THE APPLICATION WILL BE DEEMED FILED ON THE FIRST APPLICABLE DESIGNATED APPLICATION DATE AFTER ALL REQUIRED DOCUMENTATION IS RECEIVED BY THE DEPARTMENT.

Section 711. Project delivery requirements--terms of approval for all applicants

Sec. 711. (1) An applicant shall agree that, if approved, the services provided by the CT scanner(s) shall be delivered in compliance with the following terms of ~~certificate of need~~CON approval:

(a) Compliance with these standards

(b) Compliance with applicable safety and operating standards

(c) Compliance with the following quality assurance standards:

(i) The approved CT scanners shall be operating at the applicable required volumes within the time periods specified in these standards, and annually thereafter.

(ii) The applicant shall establish a mechanism to assure that the CT scanner facility is staffed so that:

(+A) The screening of requests for CT procedures and interpretation of CT procedures will be performed by physicians with training and experience in the appropriate diagnostic use and interpretation of cross-sectional images of the anatomical region(s) to be examined, and

(2B) The CT scanner is operated by physicians and/or is operated by radiological technologists qualified by training and experience to operate the CT scanner safely and effectively.

For purposes of evaluating (ii)(+A) the department shall consider it *prima facie* evidence of a satisfactory assurance mechanism as to screening and interpretation if the applicant requires the screening of requests for and interpretations of CT procedures to be performed by physicians who are board certified or eligible in radiology or are neurologists or other specialists trained in cross-sectional imaging of a specific organ system. For purposes of evaluating (ii)(2B) the department shall consider it *prima facie* evidence of a satisfactory assurance mechanism as to the operation of a CT scanner if the applicant requires the CT scanner to be operated by a physician or by a technologist registered by the American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT). However, the applicant may submit and the department may accept other evidence that the applicant has established a mechanism to assure that the CT scanner facility is appropriately and adequately staffed as to screening, interpretation, and/or operation of a CT scanner.

(iii) The applicant shall employ or contract with a radiation physicist to review the quality and safety of the operation of the CT scanner.

(iv) The applicant shall assure that at least one of the physicians responsible for the screening and interpretation as defined in subsection (ii)(+A) will be in the CT facility or available on a 24-hour basis (either on-site or through telecommunication capabilities) to make the final interpretation.

(v) In the case of an urgent or emergency CT scan, the applicant shall assure that a physician so authorized by the applicant to interpret initial scans will be on-site ~~OR AVAILABLE THROUGH TELECOMMUNICATION CAPABILITIES~~ within 1 hour following completion of the scanning procedure to render an initial interpretation of the scan. A final interpretation shall be rendered by a physician so

authorized under subsection (ii)(~~4A~~) within 24 hours.

(vi) The applicant shall have, within the CT scanner facility, equipment and supplies to handle clinical emergencies that might occur within the CT unit, with CT facility staff trained in CPR and other appropriate emergency interventions, and a physician on site in or immediately available to the CT scanner at all times when patients are undergoing scans.

(vii) Fixed CT scanner services at each facility shall be made available 24 hours a day for emergency patients.

(viii) The applicant shall accept referrals for CT scanner services from all appropriately licensed practitioners.

(ix) The applicant shall establish and maintain: (a) a standing medical staff and governing body (or its equivalent) requirement that provides for the medical and administrative control of the ordering and utilization of CT patient procedures, and (b) a formal program of utilization review and quality assurance. These responsibilities may be assigned to an existing body of the applicant, as appropriate.

(x) The applicant, to assure that the CT scanner will be utilized by all segments of the Michigan population, shall:

(~~aA~~) not deny CT scanner services to any individual based on ability to pay or source of payment;

(~~bB~~) provide CT scanning services to any individual based on the clinical indications of need for the service; and

(~~cC~~) maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(xi) The applicant shall participate in a data collection network established and administered by the department ~~OR ITS DESIGNEE~~. The data may include, but is not limited to, annual budget and cost information, operating schedules, through-put schedules, demographic and diagnostic information, the volume of care provided to patients from all payor sources, and other data requested by the department, and approved by the commission. The applicant shall provide the required data on a separate basis for each separate and distinct site or unit as required by the department; in a format established by the department; and in a mutually agreed upon media. The department may elect to verify the data through on-site review of appropriate records.

(xii) Equipment to be replaced shall be removed from service.

(xiii) ~~Within 10 days after beginning operation of a CT scanner, t~~The applicant shall provide the department with a notice stating the ~~first date on which~~ the approved CT scanner ~~SERVICE AND ITS UNIT(S) began operating~~IS PLACED IN OPERATION AND SUCH NOTICE SHALL BE SUBMITTED TO THE DEPARTMENT CONSISTENT WITH APPLICABLE STATUTE AND PROMULGATED RULES.
(XIV) AN APPLICANT SHALL PARTICIPATE IN MEDICAID AT LEAST 12 CONSECUTIVE MONTHS WITHIN THE FIRST TWO YEARS OF OPERATION AND CONTINUE TO PARTICIPATE ANNUALLY THEREAFTER.

(2) The agreements and assurances required by this section shall be in the form of a certification authorized by the governing body of the applicant or its authorized agent.

(3) The operation of and referral of patients to the CT scanner shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

Section 812. Project delivery requirements - additional terms of approval for applicants involving mobile CT scanners

Sec. 812. (1) In addition to the provisions of Section ~~711~~, an applicant for a mobile CT scanner shall agree that the services provided by the mobile CT scanner(s) shall be delivered in compliance with the following terms of ~~certificate of need~~CON approval:

(a) A host facility shall submit only one ~~certificate of need~~CON application for a CT scanner for review at any given time.

(b) A mobile CT scanner with an approved ~~certificate of need~~CON shall notify the Michigan

Department of ~~Public COMMUNITY~~ Health, ~~Division of Construction~~, prior to ~~dropping ENDING SERVICE WITH~~ an existing host facility.

(c) A ~~certificate of need~~CON shall be required to add a host facility.

(d) A ~~certificate of need~~CON shall be required to change the central service coordinator.

(e) Each host facility must have at least one board certified or board eligible radiologist on its medical staff. The radiologist(s) shall be responsible for: (i) establishing patient examination and infusion protocol, and (ii) providing for the interpretation of scans performed by the mobile CT scanner.

(f) Each mobile CT scanner service must have an Operations Committee with members representing each host facility, the central service coordinator, and the central service medical director. This committee shall oversee the effective and efficient use of the CT scanner, establish the normal route schedule, identify the process by which changes are to be made to the schedule, develop procedures for handling emergency situations, and review the ongoing operations of the mobile CT scanner on at least a quarterly basis.

(g) The central service coordinator shall arrange for emergency repair services to be available 24 hours each day for the mobile CT scanner equipment as well as the vehicle transporting the equipment. In addition, to preserve image quality and minimize CT scanner downtime, calibration checks shall be performed on the CT scanner unit at least once each work day and routine maintenance services shall be provided on a regularly scheduled basis, at least once a week during hours not normally used for patient procedures.

(h) Each host facility must provide a properly prepared parking pad for the mobile CT scanner unit of sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for patients to enter the vehicle without going outside (such as a canopy or enclosed corridor). Each host facility must also provide the capability for processing the film and maintaining the confidentiality of patient records. A communication system must be provided between the mobile vehicle and each host facility to provide for immediate notification of emergency medical situations.

(i) A mobile CT scanner service shall operate under a contractual agreement that includes the provision of CT services at each host facility on a regularly scheduled basis.

(j) The volume of utilization at each host facility shall be reported to the department by the central service coordinator under the terms of Sec-~~TION 711~~-(1)(c)(xi).

(2) The agreements and assurances required by this section shall be in the form of a certification authorized by the owner or the governing body of the applicant or its authorized agent.

Section 913. Determination of CT Equivalents

Sec. 913. For purposes of these standards, CT equivalents shall be calculated as follows:

(a) Each billable procedure for the time period specified in the applicable section(s) of these standards shall be assigned to a category set forth in Table 1.

(b) The number of billable procedures for each category in the time period specified in the applicable section(s) of these standards shall be multiplied by the corresponding conversion factor in Table 1 to determine the number of CT equivalents for that category for that time period.

(c) The number of CT equivalents for each category shall be summed to determine the total CT equivalents for the time period specified in the applicable section(s) of these standards.

Table 1	Number of		Conversion		CT
Category	Billable CT		Factor		Equivalents
	Procedures				
Head Scans w/o Contrast	_____	X	1.00	=	_____
Head Scans with Contrast	_____	X	1.25	=	_____
Head Scans w/o & w Contrast	_____	X	1.75	=	_____
Body Scans w/o Contrast	_____	X	1.50	=	_____
Body Scans with Contrast	_____	X	1.75	=	_____

478 Body Scans w/o & w Contrast _____ X 2.75 = _____
479 TOTAL CT EQUIVALENTS _____
480

481 **Section ~~10~~14. Documentation of projections** |

482
483 Sec. ~~10~~14. An applicant required to project volumes of service under ~~Sections~~ Sections 3 and 4 shall |
484 specify how the volume projections were developed. This specification of projections shall include a
485 description of the data source(s) used, assessments of the accuracy of these data, and the statistical
486 method used to make the projections. Based on this documentation the department shall determine
487 whether the projections are reasonable.
488

489 **Section ~~11~~15. Effect on prior ~~certificate of need~~CON review standards; comparative reviews** |

490
491 Sec. ~~11~~15. (1) These ~~certificate of need~~CON review standards supersede and replace the ~~Certificate of~~
492 ~~Need~~CON Review Standards for Computed Tomography Scanners approved by the ~~Certificate of~~
493 ~~Need~~CON Commission ~~ON APRIL 23, 1990~~ and effective ~~November 20, 1989~~ JUNE 17, 1990.
494

495 (2) Projects reviewed under these standards shall not be subject to comparative review.
496

**CON REVIEW STANDARDS
FOR CT SCANNER SERVICES**

RURAL MICHIGAN COUNTIES ARE AS FOLLOWS:

<u>ALCONA</u>	<u>HILLSDALE</u>	<u>OGEMAW</u>
<u>ALGER</u>	<u>HURON</u>	<u>ONTONAGON</u>
<u>ANTRIM</u>	<u>IOSCO</u>	<u>OSCEOLA</u>
<u>ARENAC</u>	<u>IRON</u>	<u>OSCODA</u>
<u>BARAGA</u>	<u>LAKE</u>	<u>OTSEGO</u>
<u>CHARLEVOIX</u>	<u>LUCE</u>	<u>PRESQUE ISLE</u>
<u>CHEBOYGAN</u>	<u>MACKINAC</u>	<u>ROSCOMMON</u>
<u>CLARE</u>	<u>MANISTEE</u>	<u>SANILAC</u>
<u>CRAWFORD</u>	<u>MASON</u>	<u>SCHOOLCRAFT</u>
<u>EMMET</u>	<u>MONTCALM</u>	<u>TUSCOLA</u>
<u>GLADWIN</u>	<u>MONTMORENCY</u>	
<u>GOGEBIC</u>	<u>OCEANA</u>	

SOURCE:

65 F.R., P. 82238 (DECEMBER 27, 2000).
STATISTICAL POLICY OFFICE
OFFICE OF INFORMATION AND REGULATORY AFFAIRS
UNITED STATES OFFICE OF MANAGEMENT AND BUDGET